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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,833	11/30/2001	Philip E. Thorpe	4001.002299	8102

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/998,833

**Applicant(s)**

THORPE ET AL.

**Examiner**

Brandon J Fetterolf, PhD

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-10,23-27,41 and 49-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 4-10,23-27,41 and 49-68 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 4-10, 23-27, 41, 49-50, 57-58, 61-65, and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second chemotherapeutic agent or a compound that interferes with tubulin activity, classified in class 424, subclass 133.1; class 514, subclass 34, 691.
- II. Claims 4-10, 23-27, 41, 51-52, 61-62, 66-67, and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second anti-angiogenic agent., classified in class 424, subclass 133.1; class 514, subclass 12.
- III. Claims 4-10, 23-27, 41, 53-54, 61-65, and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface

of blood vessels of the vascularized tumor and at least a second inflammatory cytokine, classified in class 424, subclass 133.1, class 514, subclass 8.

- IV. Claims 4-10, 23-27, 41, 55 and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second therapeutic agent such as  $H_2O_2$ , classified in class 424, subclass 133.1; class 514, subclass 714.
- V. Claims 4-10, 23-27, 41, 56 and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second therapeutic agent such as thrombin, classified in class 424, subclass 94.64.
- VI. Claims 4-10, 23-27, 41, 59-60, 61-65, and 68, as specifically drawn to a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to said animal a therapeutically effective combination of at least a pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second calcium-flux inducing or calcium ionophore agent, classified in class 424, subclass 133.1.

The inventions are distinct, each from the other because of the following reasons:

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The invention of Groups I-VI are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group I is drawn specifically to a method of treating an animal having a vascularized tumor by administering simultaneously or sequentially an antibody and a chemotherapeutic agent such as Taxol, whereas Group IV is drawn to a method of treating an animal having a vascularized tumor by administering simultaneously or sequentially an antibody and  $H_2O_2$ .

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and a search of the literature required for one group is not required for another group restriction for examination purposes as indicated is proper.

### *Species election*

Group I (Claims 4 and 49) is generic to a plurality of disclosed patentably distinct species comprising chemotherapeutic agents and agents which interfere with tubulin activity such as those listed in Table B which differ at least in mechanism of action and structural identity.

**(Note: If applicant elects as a species a compound from Table B not disclosed in claims 50 or 58, claims 50 and 58 will be withdrawn from consideration as being drawn to a non-elected species)**

Group II (Claims 4 and 51) are generic to a plurality of disclosed patentably distinct species comprising compounds that are anti-angiogenic such as those listed in Table C which differ at least in mechanism of action and structural identity.

**(Note: If applicant elects as a species a compound from Table C not disclosed in claim 52, claim 52 will be withdrawn from consideration as being drawn to a non-elected species)**

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant transverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF



**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**